

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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AUDREY DANG, Individually and On Behalf of  
All Others Similarly Situated,

Plaintiff,

vs.

GPC BIOTECH AG, BERND SEIZINGER, M.D.,  
PH.D., MARTINE GEORGE, M.D., and MARCEL  
ROZENCWEIG, M.D.,

Defendants.

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**Civil Action No. 07-cv-07476-DC**

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

Plaintiff, Audrey Dang, ("Plaintiff"), alleges the following based upon the investigation by Plaintiff's counsel, which included, among other things, a review of the defendants' public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding GPC Biotech AG ("GPC" or the "Company"), securities analysts' reports and advisories about the Company, and information readily available on the Internet, and Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

**NATURE OF THE ACTION AND OVERVIEW**

1. This is a federal class action on behalf of purchasers of GPC's securities between December 5, 2005 and July 24, 2007, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. GPC is a biopharmaceutical company engaged in the discovery, development and commercialization of new drugs to treat cancer. During the Class Period, the Company's lead product candidate was satraplatin, an orally administered platinum-based compound intended for use as a chemotherapy treatment.

3. Prior to, and throughout the Class Period, GPC reported positive test results in the evaluation of satraplatin. Further, the Company repeatedly stated that satraplatin showed promising safety and efficacy as demonstrated by "significant improvement" in progression-free survival ("PFS") in a randomized study of first-line treatment of patients with hormone-refractory prostate cancer ("HRPC"). Throughout the Class Period, satraplatin was evaluated in a Phase 3 trial entitled SPARC (Satraplatin and Prednisone Against Refractory Cancer), a second-line chemotherapy treatment for patients with HRPC. The Company reported positive results from the Phase 3 SPARC trial, and indicated that data from the trial would form the Company's New Drug Application ("NDA") with the U.S. Food & Drug Administration ("FDA"). The Company reported a 40 percent reduction in risk of disease progression for study participants who received satraplatin, and reported that the study data showed that the results for PFS were highly statistically significant. Subsequently, the PFS measure would serve as a primary endpoint in the Company's NDA submission to the FDA for satraplatin.

4. The Company's investors were shocked on July 20, 2007, when the FDA released its "Briefing Document" in advance of the FDA's Oncology Drugs Advisory Committee's meeting to consider the satraplatin NDA. Therein, the FDA cited five "issues" that it had with the Company's satraplatin NDA. One issue included the fact that the FDA had no prior experience with the Company's use of PFS, a primary endpoint in the NDA application, which was "clearly communicated to the Applicant during the development phase." Among other

additional issues, two independent radiology readers disagreed on the progression status of tumors in 39 percent of the patients, which raised questions about whether the primary endpoint could be reliably assessed in the clinical trial.

5. On this news, the Company's shares declined \$7.80 per share, or over 24.5 percent, to close on July 20, 2007 at \$24.00 per share, on unusually heavy trading volume. On the following trading day, the Company's shares declined an additional \$3.05 per share, to close on July 23, 2007 at \$20.95 per share.

6. Then on July 24, 2007, the FDA's advisory panel voted 12-0 to recommend delaying a decision on satraplatin until the Company gathered additional data. The advisory committee stated that interim data from the clinical test submitted by GPC didn't prove that the drug actually helped prostate cancer patients live longer, and questioned how the Company analyzed disease progression and pain reduction in the study. As a result, the FDA panel recommended delaying a decision on satraplatin until additional data was made available by the Company to determine whether satraplatin actually helped men with prostate cancer live longer. In response, the Company disclosed that it did not expect to have the necessary survival analysis for another year. On this news, the Company's shares declined an additional \$7.19 per share, or 35.36 percent, to close on July 25, 2007 at \$13.16 per share, on unusually heavy trading volume.

7. The Complaint alleges that, throughout the Class Period, defendants failed to disclose or indicate the following material adverse facts: (1) that the FDA had previously expressed disapproval regarding the Company's choice of methodology and a primary endpoint in the satraplatin studies; (2) that the Company continued to evaluate satraplatin using the disputed endpoint; (3) that the Company disregarded the FDA's previously expressed concerns about the disputed primary endpoint, and submitted the satraplatin study results to the FDA with

the disputed primary endpoint supporting its satraplatin NDA; (4) that the FDA's evaluators would be unable to determine disease progression from the Company's NDA submission; and (5) that the interim data submitted with the NDA would not allow the FDA to conclude that satraplatin was more effective than placebo in terms of overall survival.

8. As a result of defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class Members have suffered significant losses and damages.

### **JURISDICTION AND VENUE**

9. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, (15 U.S.C. §§ 78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

10. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

11. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b). Many of the acts and transactions alleged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this Judicial District. Additionally, GPC's securities are actively traded on the NASDAQ in this Judicial District.

12. In connection with the acts, conduct and other wrongs alleged in this Complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

### **PARTIES**

13. Plaintiff, Audrey Dang, as set forth in the accompanying certification, incorporated by reference herein, purchased GPC's securities at artificially inflated prices during the Class Period and has been damaged thereby.

14. Defendant GPC is a German corporation with its principal place of business located at Fraunhoferstrasse 20, D-82152 Martinsried/Munich, Germany.

15. Defendant Bernd Seizinger, M.D., Ph.D. ("Seizinger") was, at all relevant times, the Company's President, Chief Executive Officer ("CEO").

16. Defendant Martine George, M.D. ("George") was, at all relevant times, the Company's Senior Vice President of Clinical Development.

17. Defendant Marcel Rozenzweig, M.D. ("Rozenzweig") was, at all relevant times, the Company's Chief Medical Officer.

18. Defendants Seizinger, George, and Rozenzweig are collectively referred to hereinafter as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of GPC's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. Each defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and misleading. The Individual Defendants

are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

19. GPC is a biopharmaceutical company engaged in the discovery, development and commercialization of new drugs to treat cancer. During the Class Period, the Company's lead product candidate was satraplatin, an orally administered platinum-based compound intended for use as a chemotherapy treatment. Prior to, and throughout the Class Period, GPC reported positive test results in the evaluation of satraplatin. Further, the Company repeatedly stated that satraplatin showed promising safety and efficacy as demonstrated by "significant improvement" in PFS in a randomized study of first-line treatment of patients with HRPC. Throughout the Class Period, satraplatin was evaluated in a Phase 3 trial entitled SPARC (Satraplatin and Prednisone Against Refractory Cancer), a second-line chemotherapy treatment for patients with HRPC. The Company stated that PFS would serve as a primary endpoint in the submission of the Company's NDA for satraplatin to the FDA.

### **Materially False and Misleading Statements Issued During the Class Period**

20. The Class Period begins on December 5, 2005. On this day, GPC issued a press release entitled "GPC Biotech Announces Achievement of Target Enrollment in Satraplatin Phase 3 Registrational Trial (SPARC) for Second-Line Chemotherapy of Hormone Refractory Prostate Cancer." Therein, the Company, in relevant part, stated:

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced the achievement of target enrollment in the Phase 3 registrational trial of its lead drug candidate satraplatin, the only orally bioavailable platinum-based compound in advanced clinical development. More than 200

clinical sites in fifteen countries on four continents have now achieved the goal of accruing 912 patients to the SPARC (Satraplatin and Prednisone Against Refractory Cancer) trial. A number of additional patients are in screening, and the Company will allow those patients to complete the process and either be randomized into the trial or disqualified, in accordance with the trial protocol. ***The SPARC trial is a multicenter, multinational, double blind, randomized study that is assessing the safety and efficacy of satraplatin in combination with prednisone as a second-line chemotherapy in patients with hormone-refractory prostate cancer (HRPC).***

"We are excited to have achieved this major milestone in the development of satraplatin. This is indeed a significant accomplishment for GPC Biotech," said Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer. ***"The rapid accrual rate of the SPARC trial supports the need for effective second-line chemotherapy treatments for hormone-refractory prostate cancer patients. We are thus committed to completing the study and moving forward in the registration process as expeditiously as possible."***

"The accrual goal of 912 patients was reached in just over 26 months, making the SPARC trial one of the fastest accrued Phase 3 clinical trials for chemotherapy drugs in prostate cancer. This rapid enrollment was made possible by the dedication and hard work of the clinical investigators, the study site personnel and our own drug development team," said Marcel Rozencweig, M.D., Senior Vice President, Drug Development. "I would like to thank them, as well as all of the patients who participated in the trial." [Emphasis added.]

21. On December 15, 2005, the Company issued a press release entitled "GPC Biotech Begins Rolling NDA Submission for Lead Drug Candidate Satraplatin." Therein, the Company, in relevant part, stated:

December 15, 2005 – GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced that the Company has begun the rolling submission of a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for satraplatin in combination with prednisone as a second-line chemotherapy treatment for patients with hormone-refractory prostate cancer (HRPC). ***To begin the rolling NDA process, the Company has submitted to the FDA the***

*chemistry, manufacturing and controls – or CMC – section of the NDA filing.*

*"It is very gratifying for us to begin the rolling NDA submission process for our lead drug candidate satraplatin," said Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer. "Building on our recent achievement of reaching target enrollment in our Phase 3 registrational trial, it marks another important milestone in the development process of satraplatin as a potential new treatment option for patients with hormone-refractory prostate cancer. We are focused on working with regulatory authorities to efficiently move our compound through the filing and review process, with the ultimate goal of making satraplatin available to patients as quickly as possible."*

The rolling submission process enables companies that have been granted "fast track" designation by the FDA to submit sections of the NDA to the agency as they become available, allowing the review process to begin before the complete dossier has been submitted. Under U.S. regulations, within sixty days after the receipt of such a submission, the FDA will determine whether that application may be filed. The filing of an application means that the FDA has determined that the application is sufficiently complete to permit a substantive review.

The FDA's fast track programs are intended to expedite the review of drugs to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The FDA granted fast track designation to satraplatin as a second-line chemotherapy treatment for patients with HRPC in September 2003. [Emphasis added.]

22. On December 20, 2005, the Company issued a press release entitled "GPC Biotech and Pharmion Corporation Announce Partnering Agreement for Satraplatin." Therein, the Company, in relevant part, stated:

- Pharmion obtains commercial rights for satraplatin in Europe, Turkey, the Middle East, Australia and New Zealand; GPC Biotech retains rights in North America and all other territories
- Pharmion to make an upfront payment of \$37.1 million to GPC Biotech; GPC Biotech may receive up to \$270 million in total based upon the achievement of regulatory and sales milestones



- Target enrollment achieved in pivotal Phase 3 study for second-line chemotherapy in hormone-refractory prostate cancer; Pharmion expects to submit for European marketing authorization in 2007 pending concurrence with the EMEA

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) and Pharmion Corporation (NASDAQ: PHRM) today announced that the companies have entered into a co-development and license agreement for satraplatin, the only oral platinum-based compound in advanced clinical development. *Satraplatin has shown promising safety and efficacy as demonstrated by significant improvement in progression-free survival (PFS) in a randomized study of first-line treatment of patients with hormone-refractory prostate cancer (HRPC) and is currently the subject of a Phase 3 registrational trial as second-line chemotherapy treatment for patients with HRPC. Data from the pivotal Phase 3 trial are expected to form the basis of a Marketing Authorization Application (MAA) in Europe and a New Drug Application (NDA) in the U.S. for this indication. Based on data from this trial, Pharmion expects to file the MAA in Europe in 2007, pending concurrence with the EMEA.*

Under the terms of the agreement, Pharmion gains exclusive commercialization rights for Europe, Turkey, the Middle East, Australia and New Zealand, while GPC Biotech retains rights to the North American market and all other territories. *Pharmion is to provide an upfront payment of \$37.1 million to GPC Biotech*, including an \$18 million reimbursement for past satraplatin clinical development costs and \$19.1 million for funding of ongoing and certain future clinical development to be conducted jointly by Pharmion and GPC Biotech. The companies will pursue a joint development plan to evaluate development activities for satraplatin in a variety of tumor types and will share global development costs, for which Pharmion has made an additional commitment of \$22.2 million, in addition to the \$37.1 million in initial payments. Pharmion will also pay GPC Biotech \$30.5 million based on the achievement of certain regulatory filing and approval milestones, and up to an additional \$75 million for up to five subsequent EMEA approvals for additional indications. GPC Biotech will also receive royalties on sales of satraplatin in Pharmion's territories at rates of 26 to 30 percent on annual sales up to \$500 million, and 34 percent on annual sales over \$500 million. Finally, Pharmion will pay GPC Biotech sales milestones totaling up to \$105 million, based on the achievement of significant annual sales levels in the Pharmion territories. Pharmion and GPC Biotech will lead regulatory and commercial activities in their respective territories.

***Bernd R. Seizinger, M.D., Ph.D., chief executive officer of GPC Biotech, said: "We were very pleased with the significant interest in satraplatin shown by a large number of pharmaceutical and biotech firms in the U.S. and Europe. We have selected Pharmion as a partner because we believe they are ideally suited to help us fully exploit the potential of satraplatin in Europe and are strongly committed to continued development of this important compound for a variety of cancers. The deal structure provides us with significant funding but still allows GPC Biotech to retain the full commercialization rights to the U.S. market and other key pharmaceutical markets."*** Dr. Seizinger continued: "Pharmion's expertise and its strong oncology focused commercial infrastructure in Europe and other licensed territories will be critical in bringing satraplatin to patients in those countries. With the complementary expertise and the great respect that our teams have developed for one another, we look forward to a very productive relationship."

***"We believe that satraplatin has the potential to provide significant additional benefits in the well-characterized platinum treatment class, and we will work closely with GPC Biotech to get this vital therapy to physicians and patients as quickly as possible,"*** said Patrick J. Mahaffy, Pharmion's president and chief executive officer. "Satraplatin represents an important addition to our product portfolio, complementing our existing products as well as the global regulatory, clinical development and commercial organizations that support them." [Emphasis added.]

23. On February 24, 2006, the Company issued a press release entitled "GPC Biotech Raises € 36.2 Million in Private Placement with SAP Co-Founder Dietmar Hopp." Therein, the Company, in relevant part, stated:

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced that the Company has raised € 36.2 million in a private placement with two investment companies owned by the family of SAP AG co-founder Dietmar Hopp. ***GPC Biotech sold 2.86 million shares at a price of € 12.67/share.*** The newly issued shares, which were issued from authorized capital, represent 8.7% of GPC Biotech's total shares outstanding after the transaction. The Hopp family investment companies are new shareholders in the Company.

"As co-founder of SAP, the world's largest business software company and third largest independent software provider overall, Dietmar Hopp is one of the most renowned and successful

entrepreneurs in Germany and, indeed, worldwide. He is an active supporter of the life sciences industry and is known for his long-term investment strategy. We are delighted to have him invest in GPC Biotech," said Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer of GPC Biotech. ***"The funds we have raised will give us additional flexibility as we consider playing the lead role in the U.S. commercialization of our anticancer drug candidate satraplatin. Satraplatin is in a Phase 3 registrational trial in second-line hormone-refractory prostate cancer and is also being evaluated in several other clinical studies in various cancers."*** [Emphasis added.]

24. On February 27, 2006, the Company issued a press release entitled "GPC Biotech Presents New Satraplatin Clinical Data from Pharmacokinetics Study at ASCO Prostate Cancer Symposium." Therein, the Company, in relevant part, stated:

- New preclinical data on efficacy of satraplatin in prostate cancer cells and with Taxotere also presented

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced the presentation of new clinical and preclinical data on its lead drug candidate satraplatin at the ASCO Prostate Cancer Symposium: A Multidisciplinary Approach in San Francisco, California.

A poster entitled, "A Phase I Pharmacokinetic (PK)/Food Effect and Safety Study of Satraplatin," presented data from a study involving seventeen patients with advanced solid tumors. Most patients in the study were heavily pre-treated: the median number of prior chemotherapy treatments was three. ***Satraplatin appeared to be well tolerated, with no significant cardio-, renal, liver or neurological toxicities observed. Other common toxicities like nausea, vomiting and diarrhea were mild to moderate and were reported to be controlled with prophylactic oral anti-emetic therapy.*** Seven patients in the study had hormone-refractory prostate cancer (HRPC), and all of the HRPC patients had received Taxotere® (docetaxel), with a median of three prior chemotherapy regimens. Satraplatin showed evidence of anti-tumor activity in this group: one patient had a partial response (RECIST criteria), and two patients had prolonged stable disease (durations of 3.5 and five months).

\* \* \*

A second poster entitled, "Efficacy of Satraplatin, an Oral Platinum Analogue in Prostate Cancer: Synergistic Activity with Docetaxel," reviewed the preclinical results of studies evaluating the cell-killing effect of satraplatin and its metabolite on prostate cancer cells. ***In vivo and in vitro data showed that satraplatin and its active metabolite, JM-118, inhibited the growth of prostate cancer cells in a dose-dependent fashion.*** In addition, when satraplatin or JM-118 was combined in vitro with Taxotere, a synergistic effect was demonstrated in prostate cancer cells. This synergistic effect was strongest when Taxotere was followed by JM-118. [Emphasis added.]

25. On March 15, 2006, GPC filed a Current Report with the SEC on Form 6-K.

Therein, the Company, in relevant part, stated:

***As of December 31, 2005, cash, cash equivalents, marketable securities and short-term investments totaled (euro) 95.2 million (December 31, 2004: (euro) 131.0 million), including (euro) 1.6 million in restricted cash. The net cash burn was (euro) 47.3 million for 2005.*** Net cash burn is derived by adding net cash used in operating activities ((euro) 42.8 million) and purchases of property, equipment and licenses ((euro) 4.5 million). The figures used to calculate net cash burn are contained in the Company's consolidated statements of cash flows for the twelve-month period ended December 31, 2005. Net cash burn was (euro) 10.8 million for the fourth quarter of 2005, (euro) 12.9 million for the third quarter of 2005, (euro) 11.9 million for the second quarter of 2005 and (euro) 11.6 million for the first quarter of 2005.

***Of note, in the first quarter of 2006, the Company received an additional (euro) 67.5 million from an upfront development-related payment of (euro) 31.3 million from its partner Pharmion in connection with the co-development and license agreement signed in December 2005 and (euro) 36.2 million through a private placement with two investment companies owned by SAP co-founder Dietmar Hopp and his son, respectively.***

"Our financial results for 2005 continue to reflect our expanding efforts to successfully develop our anticancer pipeline, especially satraplatin," said Mirko Scherer, Ph.D., Senior Vice President and Chief Financial Officer. ***We expect revenues to approximately double in 2006 compared to 2005.*** For 2006 we expect R&D expenses to increase moderately compared to 2005 as regulatory-related expenses increase and we initiate new and expand existing clinical trials. ***Fortunately, our agreement with Pharmion provides us substantial development-related funding as we move***

*satraplatin forward. This important collaboration, in addition to our recent private placement, puts us in a strong financial position at such an important time for our Company."*

*"During 2005, we took critically important steps to build a sustainable future for GPC Biotech," said Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer. "We had several key achievements with our lead drug candidate satraplatin, including reaching target accrual in December in our Phase 3 registrational trial - the SPARC trial - making this one of the fastest-accruing Phase 3 trials for a chemotherapy drug ever to be conducted in prostate cancer. Also in December, we started the rolling NDA submission with the U.S. FDA. In addition to advancing the registrational trial in prostate cancer, we initiated several additional clinical trials for satraplatin, to broadly explore its anti-cancer activity in various other important tumor types, such as breast cancer and non-small cell lung cancer. The year culminated with the signing of a co-development and license agreement with Pharmion for the commercialization of satraplatin in Europe and certain other territories. Under this agreement, we could receive up to \$270 million in total payments based upon the achievement of regulatory and sales milestones, in addition to significant royalties on net sales. We also advanced a second anticancer drug candidate - the monoclonal antibody 1D09C3 - into the clinic and acquired substantially all of the assets and hired many of the discovery scientists of another biotechnology company to enhance our own oncology drug discovery engine."*

*Dr. Seizinger continued, "The year 2006 promises to be even more important as we expect to see efficacy data from our Phase 3 registrational trial for satraplatin. Provided these data are positive, our goal is to then complete the NDA filing for marketing approval of satraplatin in the U.S. by the end of this year and file through our partner Pharmion in Europe in the first quarter of 2007. We look forward to another successful year as we continue to drive forward satraplatin, as well as our other anticancer programs."*

#### ***Highlights since third quarter of 2005 update***

##### **Satraplatin**

- Signing of co-development and license agreement with Pharmion for the commercialization of satraplatin in Europe, the Middle East, Australia and New Zealand, involving a payment of \$37.1 ((euro) 31.3) million already received by

GPC Biotech and in total payments of up to \$270 million based upon the achievement of regulatory and sales milestones plus royalties

- Satraplatin Phase 3 registrational trial (SPARC) fully accrued with a total of 950 patients
- Start rolling NDA submission for satraplatin - CMC section submitted to U.S. FDA

\* \* \*

***Additional achievements***

- Private placement with two investment companies owned by SAP co-founder Dietmar Hopp and his son, respectively, raising (euro) 36.2 million

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***GPC Biotech also provided an update on the SPARC trial***, which is evaluating satraplatin plus prednisone as a second-line chemotherapy treatment for hormone-refractory prostate cancer (HRPC). The Company reported that a total of 950 patients had been enrolled in the trial, with 60% of patients from Europe, 27% from the U.S. and Canada and 13% from South America. The Company also reported that the independent Data Monitoring Board for the SPARC trial has now set a date for the interim efficacy analysis, which will be held in late April. ***The Company reiterated its expectation that the trial will continue to its completion, with full progression-free survival data available in the second half of 2006.*** [Emphasis added.]

26. On April 3, 2006, the Company issued a press release entitled "GPC Biotech Presents New Satraplatin Pre-clinical Data at AACR." Therein, the Company, in relevant part, stated:

- Therapeutic synergism in vivo when satraplatin is combined with Taxotere® (docetaxel) in non-small cell lung cancer model
- Strong synergistic effect when satraplatin's active metabolite, JM-118, is combined with Herceptin® (trastuzumab) in breast cancer cells



GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced the presentation of new pre-clinical data on its lead drug candidate satraplatin at the 97th Annual Meeting of the American Association for Cancer Research (AACR) in Washington, DC.

***"The data presented at AACR are supportive of the clinical work we have underway to explore the potential of satraplatin in a variety of combination therapies and cancer settings,"*** said Marcel Rozenzweig, M.D., Senior Vice President, Drug Development. "We currently have ongoing two Phase 1 trials evaluating satraplatin in combination with Taxotere in advanced solid tumors. We also have underway a Phase 2 study evaluating satraplatin in metastatic breast cancer, and we expect to further explore satraplatin in this treatment setting in combination with other therapies, such as Herceptin."

A poster entitled, "Synergistic antitumor activity of the combination of satraplatin and docetaxel in H460 human non-small cell lung carcinoma xenografted in nude mice," (Abstract #563) ***showed results from in vivo studies evaluating the efficacy of satraplatin and Taxotere® (docetaxel), both individually and in combination, using various dosing and treatment schedules. Within the range of doses and schedules tested, a combination of the two compounds administered sequentially results in therapeutically synergistic effects – i.e., superior to the best result that could be obtained with either agent administered individually – with no apparent increase in toxicity compared to either single agent in this tumor model.*** Results evaluating satraplatin and Taxol® (paclitaxel) in this non-small cell lung cancer model were presented in late 2005. The pre-clinical results presented at AACR build on previous data evaluating satraplatin in combination with Taxotere in cells and may be useful in developing appropriate dosing schedules for clinical testing of a combination therapy of satraplatin and Taxotere.

A poster entitled, "Synergistic in vitro anticancer activity of JM118, a metabolite of satraplatin, in combination with Herceptin," (Abstract #1350) evaluated satraplatin's active metabolite, JM118, in combination with Herceptin® (trastuzumab) against SKBR-3 breast cancer cells, which are known to be sensitive to Herceptin. ***The data showed that, within the range of doses and schedules tested, both concurrent and sequential exposure of the cells to these two compounds resulted in strong synergistic cytotoxic activity.*** GPC Biotech currently has underway a Phase 2 trial evaluating satraplatin in patients with metastatic breast cancer. The Company is conducting this study to

gain more insight into the activity of satraplatin in this important cancer area. The data presented support further exploration of the combination of satraplatin and Herceptin in breast cancer patients. [Emphasis added.]

27. On April 25, 2006, the Company issued a press release entitled "Independent Data Monitoring Board Recommends that GPC Biotech Continue Satraplatin Phase 3 Trial as Planned." Therein, the Company, in relevant part, stated:

- **Data Monitoring Board Reports Design and Conduct of Trial Remain Sound**
- **SPARC Trial Passes Futility Analysis**
- **Full Progression Free Survival Data Expected in Fall 2006**

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced that the independent Data Monitoring Board (DMB) for the satraplatin Phase 3 registrational trial SPARC (Satraplatin and Prednisone Against Refractory Cancer) in second-line chemotherapy for hormone-refractory prostate cancer has held its planned meeting to review interim safety and efficacy data from the study. *As expected, the DMB recommended that the trial should continue to completion.*

*The DMB analyzed the efficacy data as assessed by the blinded independent progression review panel on the first 354 progression-free survival (PFS) events and also reviewed the safety data from the first 593 patients who had been randomized in the trial and had completed at least one cycle of treatment. After reviewing the data, the DMB reported that the design and conduct of the trial remained sound. In addition, the DMB determined that the SPARC trial had also passed the pre-defined futility analysis. The SPARC trial, therefore, continues to completion and GPC Biotech remains blinded to the study data.*

*"We are delighted that the independent Data Monitoring Board made this recommendation and that satraplatin passed the futility analysis," said Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer. "The results of this planned interim analysis are as expected – namely that the Board has recommended that the SPARC trial continue to its completion. We look forward to reporting the final PFS results from the trial this fall and, if the data are positive, we anticipate completing the NDA filing by the end of 2006. In parallel to completing the registrational trial, we*



will continue to initiate additional clinical trials with satraplatin in other cancer indications and in combination with other anticancer treatments." [Emphasis added.]

28. On June 6, 2006, the Company issued a press release entitled "GPC Biotech Presents New Satraplatin Clinical Data from Two Pharmacokinetics Studies at ASCO." Therein, the Company, in relevant part, stated:

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced the presentation of new clinical data on its lead drug candidate satraplatin, currently in a fully enrolled Phase 3 trial, at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in Atlanta, Georgia.

A poster entitled, "Phase 1 Study of the Effects of Hepatic Impairment on the Pharmacokinetics (PK) and Safety of Satraplatin in Patients with Refractory Non-Hematologic Cancer," presented study data on 19 patients with advanced solid tumors and with varying degrees of hepatic impairment (reduced liver function). The study was designed to show the effect of hepatic impairment on the pharmacokinetics of satraplatin in patients with advanced forms of cancer. Most patients in the study were heavily pre-treated. As this study is still ongoing, the data reported are considered preliminary. ***Satraplatin appears to be well tolerated in patients with mild to moderate liver impairment. As expected, the main toxicities observed thus far have been hematologic – anemia, thrombocytopenia (decrease in platelets in the blood) and neutropenia (decrease in white blood cells). Non-hematologic toxicities like diarrhea, anorexia, and fatigue have been mild. No significant cardio-, liver or neurological toxicities have yet been observed.***

A second poster entitled, "Phase 1 Study of the Effects of Renal Impairment on the Pharmacokinetics and Safety of Satraplatin in Patients with Refractory Non-Hematologic Cancer," presented study data on 24 patients with advanced solid tumors and with varying degrees of renal impairment (reduced kidney function). The study was designed to show the effect of renal impairment on the pharmacokinetics of satraplatin in patients with advanced forms of cancer. As this study is still ongoing, the data reported are considered preliminary. ***Satraplatin appears to be well tolerated in these patients. As expected, the main hematological toxicities observed to date have been anemia and thrombocytopenia.*** Common toxicities like nausea, vomiting,

diarrhea, fatigue and anorexia have to date been mild. *No significant cardio-, renal, liver or neurological toxicities have yet been observed.* [Emphasis added.]

29. On June 8, 2006, the Company issued a press release entitled "Independent Data Monitoring Board Recommends that Satraplatin Phase 3 Trial Continue as Planned." Therein, the Company, in relevant part, stated:

• **Full Progression Free Survival Data Expected in Fall 2006**

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) and Pharmion Corporation (NASDAQ: PHRM) today announced that the independent Data Monitoring Board (DMB) for the satraplatin Phase 3 registrational trial SPARC (Satraplatin and Prednisone Against Refractory Cancer) in second-line chemotherapy for hormone-refractory prostate cancer has held a meeting to review an interim analysis of overall survival data from the study. *The DMB recommended the trial continue as planned, per protocol.*

*No safety concerns were raised by the DMB, and they recommended that the trial continue as planned, without changes. The SPARC trial, therefore, continues to completion and GPC Biotech and Pharmion remain blinded to the study data.* As previously communicated, the companies expect the full progression free survival (PFS) data to be available in the fall of this year. *PFS remains the endpoint of the SPARC trial for accelerated approval in the U.S. and is also the basis, along with supporting overall survival data, for approval in Europe.*

*"We look forward to reporting the final PFS results from the trial this fall.* If the data are positive, we anticipate completing the NDA filing by the end of 2006, and we expect that Pharmion will file its MAA with the European regulatory authorities in the first quarter of 2007," said Marcel Rozencweig, M.D., Senior Vice President, Drug Development and Chief Medical Officer of GPC Biotech. "In parallel to completing the registrational trial, we will continue to initiate additional clinical trials with satraplatin in other cancer indications and in combination with other anticancer treatments." [Emphasis added.]

30. On July 12, 2006, the Company issued a press release entitled "GPC Biotech Submits Non-Clinical Section of Rolling NDA for Lead Oncology Drug Candidate Satraplatin."

Therein, the Company, in relevant part, stated:

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced that the Company has submitted the non-clinical section of the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for satraplatin in combination with prednisone as a second-line chemotherapy treatment for patients with hormone-refractory prostate cancer (HRPC). The Company submitted the chemistry, manufacturing and controls – or CMC – section of the NDA in December 2005 and anticipates completing the NDA submission by the end of 2006.

"The non-clinical section is the second of three parts necessary to complete the NDA submission. We are very pleased that we continue to make such good progress in advancing satraplatin toward the market and that we remain on track with our timelines," said Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer. "The second half of 2006 promises to be of seminal importance for GPC Biotech as we expect to have the final data on progression-free survival from our SPARC registrational trial in the fall and complete the NDA filing by the end of this year."

The FDA granted "fast track" designation to satraplatin as a second-line chemotherapy treatment for patients with HRPC in September 2003. The FDA's fast track programs are intended to expedite the review of drugs to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

The rolling submission process enables companies that have been granted fast track designation to submit sections of the NDA to the agency as they become available, allowing the review process to begin before the complete dossier has been submitted.

31. On September 24, 2006, the Company issued a press release entitled "GPC Biotech and Pharmion Announce Positive Results from the Satraplatin Pivotal Phase 3 Trial and Achievement of the Progression-Free Survival Endpoint." Therein, the Company, in relevant part, stated:

- ***40% Reduction in Risk of Disease Progression Seen with Satraplatin Compared to Control***

- ***Highly Statistically Significant Results Seen for Progression-Free Survival ( $p < 0.00001$ )***
- U.S. Regulatory Submission Expected by Year-End 2006, European Filing in H1 2007

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) and Pharmion Corporation (NASDAQ: PHRM) ***today announced positive topline results for the double-blinded, randomized satraplatin Phase 3 registrational trial, the SPARC trial*** (Satraplatin and Prednisone Against Refractory Cancer). The trial is evaluating satraplatin plus prednisone versus placebo plus prednisone as a second-line treatment in 950 patients with hormone-refractory prostate cancer (HRPC). ***The study data show that the results for progression-free survival (PFS) are highly statistically significant ( $p < 0.00001$ ) using the protocol-specified log-rank test. PFS is the primary endpoint for submission for accelerated approval in the U.S. and will also serve as the primary basis for a Marketing Authorization Application (MAA) in Europe.***

Using the protocol-specified hazard ratio, which measured the overall risk of disease progression, ***patients in the SPARC trial who received satraplatin plus prednisone had a 40% reduction in the risk of disease progression*** (hazard ratio of 0.6; 95% Confidence Interval: 0.5-0.7) compared with patients who received prednisone plus placebo. ***The improvement seen in progression-free survival by patients treated with satraplatin increased over time. Progression-free survival at the median (50th percentile) demonstrated a 13% improvement in patients who received satraplatin plus prednisone (11 weeks) compared to patients who received prednisone plus placebo (9.7 weeks). Progression-free survival at the 75th percentile showed an 89% improvement for patients in the satraplatin arm (36 weeks) versus patients in the placebo arm (19 weeks).*** At 6 months, 30% of patients in the satraplatin arm had not progressed, compared to 17% of patients in the control arm. At 12 months, 16% of patients who received satraplatin had not progressed, compared to 7% of patients in the control arm. All of these analyses were conducted on an intent-to-treat basis.

\* \* \*

"Patients with advanced hormone-refractory prostate cancer are in urgent need of new treatment options. ***We are excited about the highly statistically significant improvement in progression-free survival demonstrated by satraplatin in our Phase 3***

*registrational trial. Importantly, the difference in progression-free survival increases over time in favor of the satraplatin group," said Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer of GPC Biotech. "Based on the positive data announced today, we will move forward as rapidly as possible with the FDA with the goal of completing the filing for marketing approval of satraplatin in the U.S. before the end of this year."*

\* \* \*

*"We believe that these results demonstrate the benefits that satraplatin can provide men with advanced prostate cancer. In addition, the oral administration of satraplatin offers the patient the convenience of outpatient therapy and the potential for greater dosing coordination with other cancer therapies," said Patrick J. Mahaffy, President and Chief Executive Officer of Pharmion Corporation. "Pharmion remains focused on preparing its marketing authorization application, which we plan to file with the European regulatory authorities in the first half of 2007. We have worked closely with GPC Biotech since licensing the European and other international rights to satraplatin last December and look forward to continuing our partnership as we move through the regulatory process towards commercialization."*

*The SPARC trial is a double-blinded, randomized, placebo-controlled multinational Phase 3 trial assessing satraplatin plus prednisone as a second-line chemotherapy treatment for patients with HRPC.* A total of 950 patients were accrued to the trial at more than 200 clinical sites in fifteen countries on four continents. The companies plan to submit data from the SPARC trial for presentation at an upcoming major medical conference.

GPC Biotech intends to move forward with the U.S. Food and Drug Administration (FDA) with the goal of completing the submission of the rolling New Drug Application (NDA) by the end of 2006 for approval to market satraplatin. Pharmion Corporation intends to file an MAA to the European Medicines Agency (EMA) in the first half of 2007. [Emphasis added.]

32. On November 9, 2006, the Company issued a press release entitled "GPC Biotech Reports Financial Results for Third Quarter and First Nine Months of 2006." Therein, the Company, in relevant part, stated:

- Revenues more than tripled in third quarter 2006 compared to the same period in 2005

- Revenue guidance increased for the full year 2006; now expected to exceed € 22 million
- Cash and equivalents € 114 million (~\$145 million) as of September 30, 2006

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX 30; NASDAQ: GPCB) today reported financial results for the third quarter and first nine months ended September 30, 2006.

\* \* \*

*"Our revenues more than tripled in the third quarter of 2006 compared to the same period in 2005 due to our co-development and license agreement with Pharmion,"* said Mirko Scherer, Ph.D., Senior Vice President and Chief Financial Officer. *"With the revenue that we have already recognized this year under the terms of this deal, we are able to increase our guidance for the full year 2006.* Originally, we expected to approximately double the 2005 revenue amount of € 9.3 million to just under € 19 million. We now expect to book revenues of more than € 22 million for 2006."

*Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer, said: "In the third quarter of 2006, we achieved a landmark event in the corporate history of GPC Biotech, with the announcement of positive results on progression-free survival from our Phase 3 registrational trial with our lead anticancer drug candidate satraplatin. These results will form the basis of our NDA filing, which we expect to submit to the FDA in the next six to twelve weeks, with the goal of filing by the end of this year. They will also serve as the basis for our partner Pharmion to move forward with the MAA filing in Europe in the first half of 2007. We are also moving forward aggressively to further build our marketing and sales infrastructure in the U.S. for the commercialization of satraplatin."*

#### **Highlights from the third quarter of 2006 and later**

- *Positive results announced from satraplatin pivotal Phase 3 SPARC trial*
  - *Highly statistically significant results seen for progression-free survival endpoint ( $p < 0.00001$ )*
  - *40% reduction in risk of disease progression seen with satraplatin compared to control [Emphasis added.]*



33. On January 24, 2007, the Company issued a press release entitled "GPC Biotech Raises € 33.6 Million (~\$43.7) in Private Placement." Therein, the Company, in relevant part, stated:

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) has raised gross proceeds of € 33.6 million (approximately \$43.7 million) in a private placement with institutional investors. ***GPC Biotech sold 1,564,587 million shares at a price of € 21.50/share*** and will receive the proceeds upon registration of the corresponding capital increase. The share price and the number of shares were determined by an accelerated bookbuilding procedure with an underwriter.

With the issuance of these new shares, GPC Biotech's total registered share capital will increase from € 33,103,337 to € 34,667,927. The newly issued shares, which will be taken from authorized capital, will represent 4.51% of GPC Biotech's total shares outstanding after the transaction.

***"With the announcement this past fall of positive data from the satraplatin Phase 3 trial in second-line hormone refractory prostate cancer, we were able to accelerate the building of our commercialization infrastructure in the U.S.," said Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer. "The funds we have raised will assist us both in aggressively moving forward with commercialization activities, as well as continuing to expand the development of satraplatin in other cancer settings."***

The listing of the new shares on the Frankfurt Stock Exchange (Prime Standard) is expected to take place in August 2007. To ensure a proper allocation and delivery of the placed shares to investors, large shareholders of GPC Biotech have transferred to the underwriter existing shares of the Company in the form of a securities loan. The underwriter will make use of such shares only to perform the placement to institutional investors. [Emphasis added.]

34. On February 16, 2007, the Company issued a press release entitled "GPC Biotech Submits NDA for Lead Oncology Drug Candidate Satraplatin." Therein, the Company, in relevant part, stated:

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced that the Company has

completed the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for satraplatin for the treatment of patients with androgen independent (hormone refractory) prostate cancer (HRPC) who have failed prior chemotherapy. ***The Company submitted the third and final portion of the NDA - the clinical section, which is based primarily on data from the SPARC Phase 3 registrational trial.*** The trial enrolled 950 patients and showed highly statistically significant results for prolonging progression-free survival (PFS). The FDA has up to 60 days to determine whether the application meets the regulatory requirements for filing and thus will be reviewed by the agency. The Company will also be notified during that timeframe if priority review status has been granted.

***"The submission of the NDA for satraplatin capsules is a major milestone in the corporate history of GPC Biotech," said Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer. "We will work closely with the FDA during the review process to move the application forward as expeditiously as possible. We believe that, if approved, satraplatin has the potential to become an important new treatment option for advanced prostate cancer patients who today have very little hope. We are currently building our commercial infrastructure in the U.S. to prepare for the potential launch of satraplatin so that it will be available for these patients as quickly as possible." [Emphasis added.]***

35. On February 23, 2007, the Company issued a press release entitled "Satraplatin Shown to Significantly Reduce Risk of Disease Progression in Advanced Hormone-Refractory Prostate Cancer Patients." Therein, the Company, in relevant part, stated:

- ***Highly Statistically Significant Results for Improvement in Progression-Free Survival***
- Progression-Free Survival Results Consistent Irrespective of Prior Chemotherapy Treatment, including Taxotere®
- Satraplatin was Well Tolerated with Myelosuppression the Most Commonly Observed Toxicity
- Data Being Presented Today at ASCO Prostate Cancer Symposium in Orlando, Florida

\* \* \*



GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) and Pharmion Corporation (NASDAQ: PHRM) today announced that final progression-free survival (PFS) results for the double-blind, randomized satraplatin Phase 3 registrational trial, the SPARC trial (Satraplatin and Prednisone Against Refractory Cancer) are being presented today at the ASCO Prostate Cancer Symposium in Orlando, Florida. The trial is evaluating satraplatin plus prednisone versus placebo plus prednisone in 950 patients with hormone-refractory prostate cancer (HRPC) who have failed prior chemotherapy. All analyses of PFS being presented were conducted on an intent-to-treat basis.

***The study data show that satraplatin significantly reduces the risk of disease progression in these patients using the protocol-specified log-rank test.*** The hazard ratio of 0.6 (95% CI: 0.5-0.7,  $p < 0.00001$ ), which was first reported in September 2006, adjusted for nine pre-specified prognostic factors. Using a more conservative analysis, which adjusted only for the three pre-specified stratification factors, the hazard ratio is 0.67 (95% CI: 0.57-0.77,  $p = 0.0000003$ ). These hazard ratio numbers correspond to a reduction in relative risk of disease progression of 40% and 33%, respectively. Both analyses are being presented today in Orlando.

In accordance with the recommendation of the independent Data Monitoring Board for the SPARC trial, patients who have not progressed continue to be treated and all patients will be followed for overall survival. Overall survival data are expected to be available later this year. GPC Biotech recently completed the New Drug Application (NDA) submission for satraplatin to the U.S. Food and Drug Administration (FDA). Pharmion expects to complete the Marketing Authorization Application (MAA) for Europe in the second quarter of 2007.

Daniel Petrylak, M.D., Associate Professor of Medicine at Columbia University College of Physicians & Surgeons, Director of the Genitourinary Oncology Program at New York-Presbyterian Hospital/Columbia, and a Principal Investigator in the SPARC trial, said: "As there are currently no approved therapies for patients with hormone-refractory prostate cancer whose disease has already failed on one chemotherapy regimen, satraplatin has the potential to address a mounting area of unmet medical need. ***The data I am presenting today show statistically significant results in progression-free survival in favor of those patients treated with satraplatin.*** These results are consistent no matter what the prior chemotherapy treatment, including Taxotere®."

*All disease progression events were adjudicated by an independent expert review committee of medical oncologists and radiologists.* The vast majority of progression events were based on radiological progressions and pain progressions. Pain associated with bone metastases is the dominant cause of morbidity in patients with metastatic HRPc. Increase in prostate specific antigen (PSA) was not part of the progression endpoint. *PFS at the median demonstrated a 14% improvement in patients who received satraplatin plus prednisone (11.1 weeks) compared to patients who received prednisone plus placebo (9.7 weeks). The improvement seen in PFS by patients treated with satraplatin increased over time. PFS at the 75th percentile showed an 81% improvement for patients in the satraplatin arm (34.6 weeks) versus patients in the placebo arm (19.1 weeks).* At six months, 30% of patients in the satraplatin arm had not progressed, compared to 17% of patients in the control arm. At twelve months, 16% of patients who received satraplatin had not progressed, compared to 7% of patients in the control arm.

\* \* \*

*Safety findings were consistent with previous clinical studies involving satraplatin.* The reported adverse reactions were mostly mild to moderate in severity. The most common adverse reactions consisted of myelosuppression (bone marrow functions): Twenty-one percent of patients in the satraplatin arm experienced grade 3 or 4 thrombocytopenia; 14 percent had leucopenia and 21 percent had neutropenia. Eight percent of patients in the satraplatin arm experienced grade 3 or 4 gastrointestinal toxicities, including nausea, vomiting, diarrhea and constipation. Five percent or less of patients in the satraplatin arm experienced grade 3 or 4 fatigue, grade 3 or 4 infections and pulmonary/respiratory grade 3 or 4 toxicities.

*"We are delighted with the strong detailed results presented today from the satraplatin SPARC Phase 3 trial," said Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer of GPC Biotech. "Moving forward, we plan to work closely with the FDA regarding our application for marketing approval of satraplatin in the U.S. We also are continuing to aggressively build our marketing and sales organization in the U.S. to prepare for a potential launch of satraplatin later this year." [Emphasis added.]*

36. On March 22, 2007, the Company issued a press release entitled "Additional Data from Satraplatin SPARC Phase 3 Trial Presented at European Association of Urology Congress."

Therein, the Company, in relevant part, stated:

**Patients treated with Satraplatin Demonstrated Statistically Significant Improvement in Pain Response and PSA Response Rates**

- Pain response rates of 24.2 percent for the satraplatin arm compared with 13.8 percent for the placebo arm ( $p=0.005$ )
- PSA response rates of 25.4 percent for the satraplatin arm compared with 12.4 percent for the placebo arm ( $p<0.001$ )

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) and Pharmion Corporation (NASDAQ: PHRM) today announced additional data from the double-blind, randomized satraplatin Phase 3 registrational trial, the SPARC trial (Satraplatin and Prednisone Against Refractory Cancer) which were presented today at the 22nd Annual European Association of Urology Congress in Berlin, Germany. The trial is evaluating satraplatin plus prednisone versus placebo plus prednisone in 950 patients with hormone-refractory prostate cancer (HRPC) who have failed prior chemotherapy.

\* \* \*

*Data presented today from the SPARC study showed that pain response rates for patients treated with satraplatin were statistically significantly superior compared to the pain response rates for those patients in the comparator arm. Pain response rates were 24.2 percent for the satraplatin plus prednisone arm compared with 13.8 percent for the placebo arm ( $p=0.005$ ).*

\* \* \*

*Data from the SPARC trial also showed that the prostate specific antigen (PSA) response rate for patients treated with satraplatin was significantly improved compared to the PSA response rate for those patients in the placebo arm. PSA response rates were 25.4 percent for the satraplatin plus prednisone arm compared with 12.4 percent for the placebo arm ( $p<0.001$ ).*

PSA response was analyzed using the widely adopted Bubley criteria of a decrease of PSA level by greater than or equal to 50 percent from baseline, with confirmation at least four weeks later.

Marcel Rozenzweig, M.D., chief medical officer and senior vice president, drug development of GPC Biotech said: "Patients with hormone-refractory prostate cancer frequently suffer from terrible

pain associated with bone metastases. *The satraplatin data presented today continue to build on the progression-free survival data already presented from the SPARC trial.*"

*"We believe the PSA response rate provides important information especially in this challenging second-line context,"* said Andrew Allen, Pharmion's chief medical officer and executive vice president. *"To see this level of response for both pain and PSA is very encouraging and provides important additional insight on the clinical profile of satraplatin in patients with advanced prostate cancer."*

The pain and PSA response analyses, in addition to the previously presented PFS data, further define satraplatin's clinical profile as a potential second-line treatment option in metastatic HRPc.

\* \* \*

*Safety findings were consistent with previous clinical studies involving satraplatin.* The most common adverse reactions consisted of myelosuppression (bone marrow functions): Twenty-one percent of patients in the satraplatin arm experienced grade 3 or 4 thrombocytopenia; 14 percent had leucopenia and 21 percent had neutropenia. Eight percent of patients in the satraplatin arm experienced grade 3 or 4 gastrointestinal toxicities, including nausea (1.3%), vomiting (1.6%), diarrhea (2.1%) and constipation (2.1%). Five percent or less of patients in the satraplatin arm experienced grade 3 or 4 fatigue, grade 3 or 4 infections and pulmonary/respiratory grade 3 or 4 toxicities. [Emphasis added.]

37. On April 16, 2007, the Company issued a press release entitled "FDA Accepts GPC Biotech's Satraplatin NDA for Filing and Grants Priority Review Status." Therein, the Company, in relevant part, stated:

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the Company's New Drug Application (NDA) for satraplatin in combination with prednisone for patients with hormone-refractory prostate cancer (HRPC) whose prior chemotherapy has failed. The Company also announced that the FDA has granted the NDA priority review status. Priority review designation is intended for those products that address significant unmet medical needs and sets the target date for FDA action at six months from the date of submission. GPC Biotech completed the rolling submission of the NDA for

satraplatin on February 15, 2007. The application will be reviewed under the provisions of 21 CFR 314 Subpart H, for accelerated approval.

*"We are pleased that the FDA has accepted our application for filing and granted it priority review status. We look forward to working closely with the agency during the review process," said Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer. "With the designation of priority review, we expect an action on the application from the FDA in August of this year and are thus moving forward with commercialization plans for satraplatin. If approved, we believe that satraplatin has the potential to become an important therapy for hormone-refractory prostate cancer patients whose disease has progressed after prior chemotherapy, an area of unmet medical need." [Emphasis added.]*

38. On May 15, 2007, the Company issued a press release entitled "GPC Biotech's Satraplatin NDA to be Reviewed by ODAC Panel on July 24, 2007." Therein, the Company, in relevant part, stated:

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced that the Company has been informed by the U.S. Food and Drug Administration (FDA) that *the New Drug Application (NDA) for satraplatin for patients with hormone-refractory prostate cancer (HRPC) whose prior chemotherapy has failed will be reviewed by the Oncologic Drugs Advisory Committee (ODAC) on July 24, 2007.* Advisory committees provide the FDA with independent advice from outside experts on issues related to human drugs and other regulated areas. Although the committees provide advice to the agency, final decisions are made by the FDA. *Earlier, the FDA had accepted for filing the Company's NDA and had granted the NDA priority review status. An action from the FDA on the application is expected in August of this year.*

*"Presentation of the satraplatin data to the Oncologic Drugs Advisory Committee is the next important milestone in the NDA review process. We remain committed to successfully completing this review as quickly as possible,"* said Marcel Rozenzweig, M.D., Chief Medical Officer and Senior Vice President, Drug Development of GPC Biotech. *"We expect an action on the application from the FDA in August of this year and are thus moving forward with commercialization plans for satraplatin. If approved, we believe that satraplatin has the potential to become an important therapy for hormone-refractory prostate cancer*

patients whose disease has progressed after prior chemotherapy, an area of significant unmet medical need." [Emphasis added.]

39. Also on May 15, 2007, the Company issued a press release entitled "GPC Biotech Reports Financial Results for the First Quarter of 2007." Therein, the Company, in relevant part, stated:

**Quarter highlighted by**

- *completion of NDA submission for satraplatin, now under priority review at the FDA*
- *presentation of important data from satraplatin SPARC Phase 3 trial at major medical conferences*

\* \* \*

Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer, said: "We have already had several key achievements in the first few months of 2007, including completion of the NDA submission for satraplatin and its acceptance for filing by the FDA. We are very pleased that FDA has granted the NDA submission priority review status and look forward to an action by the agency in August this year."

Dr. Seizinger continued: "We are very busy preparing for the possible U.S. launch of satraplatin later this year. With the acceptance of the NDA filing and the assignment of priority review by the FDA, and with the senior management of our U.S. marketing and sales organization in place, we have begun to hire the field sales force. In addition, we continue to move forward satraplatin clinical trials in other oncology indications, as well as our other development and discovery programs."

**Key Achievements: Year-to-Date 2007**

- Private placement with institutional investors raising net proceeds of € 32.6 million
- Rolling submission of an NDA for satraplatin completed and accepted for filing by the U.S. FDA
- NDA for satraplatin granted priority review status, setting target date for FDA action in August 2007



- Key progression-free survival (PFS) results as well as positive data on pain and PSA response rates from the satraplatin SPARC Phase 3 registrational trial in second-line chemotherapy for hormone-refractory prostate cancer presented at major international oncology and urology meetings
- Satraplatin Expanded Rapid Access protocol (SPERA) launched in the U.S. [Emphasis added.]

40. On May 21, 2007, the Company issued a press release entitled "Additional Efficacy Data from Satraplatin SPARC Phase 3 Investigational Trial Presented at Annual Meeting of American Urological Association." Therein, the Company, in relevant part, stated:

- Median time to pain progression is 66.1 weeks for the satraplatin arm compared with 22.3 weeks for the placebo arm
- Hazard ratio of 0.64 (95% CI: 0.51-0.79,  $p < 0.001$ ), representing a 36% reduction in the relative risk of pain progression

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) and Pharmion Corporation (NASDAQ: PHRM) today announced the presentation of additional data from the double-blind, randomized satraplatin Phase 3 registrational trial, the SPARC trial (Satraplatin and Prednisone Against Refractory Cancer). The data are being presented today at the Annual Meeting of the American Urological Association (AUA) in Anaheim, California. The SPARC trial is evaluating satraplatin plus prednisone versus placebo plus prednisone in 950 patients with hormone-refractory prostate cancer (HRPC) whose prior chemotherapy has failed. An NDA for satraplatin is currently under priority review by the U.S. FDA.

***"Patients with metastatic hormone-refractory prostate cancer frequently suffer from substantial pain associated with bone metastases. Thus, pain control for these patients constitutes a major challenge and is an important goal when caring for them,"*** said Oliver Sartor, M.D., Lank Center for Genitourinary Oncology, Dana Farber Cancer Institute, Associate Professor at Harvard Medical School, Boston, MA, and principal investigator of the SPARC trial, who is presenting the satraplatin data today. ***"In addition to the very encouraging results for progression-free survival demonstrating a 33% lower risk of progression compared to control, it is exciting to see that the SPARC trial***

***results show that treatment with satraplatin also results in a statistically significant improvement in time to pain progression."***

Data presented today showed that the median time to pain progression was 66.1 weeks for the satraplatin arm compared with 22.3 weeks for the placebo arm. The hazard ratio was 0.64 (95% CI: 0.51-0.79,  $p < 0.001$ ), which translates into a 36% reduction in the relative risk of pain progression. These results were consistent across multiple pre-defined subsets of patients, including patients treated with prior Taxotere® (docetaxel). All pain progression events were assigned by a blinded independent review committee. Complementing the time to pain progression data, pain response rates were 24.2 percent for the satraplatin plus prednisone arm (N=351) compared with 13.8 percent for the placebo arm (N=181) ( $p = 0.005$ ). Pain response rates for patients treated with prior Taxotere were 25.7 percent for the satraplatin arm compared with 13.1 percent for control ( $p < 0.015$ ). All of the findings presented today continue to build on the data previously presented from the SPARC trial.

\* \* \*

***Safety findings in the SPARC trial were consistent with previous clinical studies involving satraplatin.*** The most common adverse reactions consisted of myelosuppression (bone marrow functions): Twenty-one percent of patients in the satraplatin arm experienced grade 3 or 4 thrombocytopenia; 14 percent had leucopenia and 21 percent had neutropenia. Eight percent of patients in the satraplatin arm experienced grade 3 or 4 gastrointestinal toxicities, including nausea (1.3%), vomiting (1.6%), diarrhea (2.1%) and constipation (2.1%). Five percent or less of patients in the satraplatin arm experienced grade 3 or 4 fatigue, grade 3 or 4 infections and pulmonary/respiratory grade 3 or 4 toxicities. [Emphasis added.]

41. On June 4, 2007, the Company issued a press release entitled "Additional New Data from Satraplatin SPARC Phase 3 Investigational Trial Presented at ASCO Annual Meeting." Therein, the Company, in relevant part, stated:

- ***All pre-specified subset analyses of progression-free survival in the SPARC Phase 3 trial consistently demonstrate a reduction in relative risk of disease progression for patients receiving satraplatin.*** These analyses included prior Taxotere use, geographies, as well as presence or absence of pain.



- The two major causes of progression in the SPARC trial - radiologic progression and pain progression - were each associated with a 36% reduction in relative risk of disease progression.

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) and Pharmion Corporation (NASDAQ: PHRM) today announced the presentation of additional data from the double-blind, randomized satraplatin Phase 3 registrational trial, the SPARC trial (Satraplatin and Prednisone Against Refractory Cancer). The data are being presented today at the Annual Meeting of the American Society for Clinical Oncology (ASCO) in Chicago. The SPARC trial is evaluating satraplatin plus prednisone versus placebo plus prednisone in 950 patients with hormone-refractory prostate cancer (HRPC) whose prior chemotherapy has failed. A New Drug Application (NDA) for satraplatin is currently under priority review by the U.S. Food and Drug Administration (FDA).

"Today hormone-refractory prostate cancer patients whose chemotherapy has failed have no approved treatment options. ***The data I have presented today from the SPARC trial show that satraplatin lowers the risk of disease progression by 33% compared to control. The data are consistent across numerous pre-defined subsets, including patients previously treated with Taxotere,***" said Cora Sternberg, M.D., FACP, Chief of the Department of Medical Oncology at the San Camillo and Forlanini Hospitals, Rome, Italy and one of the principal investigators of the SPARC registrational trial. "I believe these efficacy results, together with satraplatin's manageable side effect profile, mean that, if approved, satraplatin will represent an important new therapy option for patients with advanced prostate cancer whose prior chemotherapy has failed."

The relative risk of disease progression favored satraplatin for all pre-specified patient subsets, including prior Taxotere use, geographies, and the presence or absence of pain. ***For each of the 20 subsets presented today, the reduction in relative risk of disease progression ranged from 26% to 46%,*** corresponding to hazard ratios between 0.74 and 0.54.

Disease progression in the SPARC trial was defined as the first occurrence of any of several types of progression, including radiologic tumor progression (RECIST for soft tissue lesions or two or more new lesions on a bone scan); skeletal-related events (including a bone fracture, bone surgery or initiation of bisphosphonates); symptomatic progression (pain, weight loss,

worsening of performance status); or death from any cause. Approximately 37% of patients in the trial progressed by pain and approximately 36% progressed on radiologic evidence. The hazard ratio for PFS for the subset of patients with pain progression or death was 0.64 (95% CI: 0.51-0.79,  $p=0.0001$ ), representing a 36% reduction in the relative risk of progression. The hazard ratio for PFS for the subset of patients with radiologic progression or death was 0.64 (95% CI: 0.51-0.81,  $p=0.0001$ ), representing a 36% reduction in the relative risk of progression. The hazard ratio for PFS for the subset of patients who progressed in ways other than radiologic or pain progression was 0.86 (95% CI: 0.63-1.17,  $p > 0.05$ ).

\* \* \*

PFS data as observed by the clinical site investigators were also presented today. Compared to the PFS data previously reported, these progression events were not adjudicated by the blinded independent review committee. The hazard ratio for PFS for the intent-to-treat population per investigator observation was 0.58 (95% CI: 0.50-0.67,  $p = 0.000000000002$ ). Median time to progression was 16.0 weeks for the satraplatin arm versus 6.0 weeks for control. The hazard ratio for PFS for the intent-to-treat population treated with prior Taxotere® (docetaxel) per investigator observation was 0.52 (95% CI: 0.42-0.65,  $p=0.0000000002$ ), with a median time to progression of 15.3 weeks for the satraplatin arm compared to 5.6 weeks for control. ***These data are consistent with the PFS outcomes as adjudicated by the blinded independent review committee.***

***Safety findings in the SPARC trial were consistent with previous clinical studies involving satraplatin.*** Myelosuppression (decrease in the production of blood cells by the bone marrow) was the most common adverse reaction associated with satraplatin therapy. Twenty-one percent of patients in the satraplatin arm experienced grade 3 or 4 thrombocytopenia; 14% had grade 3 or 4 leucopenia and 21% had grade 3 or 4 neutropenia. Gastrointestinal disorders were the most frequent non-hematological adverse events (occurring in 57.9% of the patients receiving satraplatin). Eight percent of patients in the satraplatin arm experienced grade 3 or 4 gastrointestinal toxicities, including nausea (1.3%), vomiting (1.6%), diarrhea (2.1%) and constipation (2.1%). Additionally, 5% or less of patients in the satraplatin arm experienced grade 3 or 4 fatigue (1.7%), grade 3 or 4 infections (4.0%) and pulmonary/respiratory grade 3 or 4 toxicities (3.0%). [Emphasis added.]

42. The statements contained in ¶¶20 – 41 were materially false and misleading when made because Defendants failed to disclose or indicate the following: (1) that the FDA had previously expressed disapproval regarding the Company's choice of methodology and a primary endpoint in the satraplatin studies; (2) that the Company continued to evaluate satraplatin using the disputed endpoint; (3) that the Company disregarded the FDA's previously expressed concerns about the disputed primary endpoint, and submitted the satraplatin study results to the FDA with the disputed primary supporting its NDA; (4) that the FDA's evaluators would be unable to determine disease progression from the Company's NDA submission; and (5) that the interim data submitted with the NDA would not allow the FDA to conclude that satraplatin was more effective than placebo in terms of overall survival.

### **The Truth Begins to Emerge**

43. On July 20, 2007, the FDA released its "Briefing Document" in advance of the Oncology Drugs Advisory Committee's meeting to consider the satraplatin NDA. Therein, the FDA, in relevant part, stated:

The pivotal study for this NDA is the SPARC study in 950 patients sponsored by the Applicant. A small EORTC study in 50 patients is submitted as a supportive study.

The SPARC study is a multicenter, multinational, double blind placebo-controlled trial with 950 patients with androgen-independent prostate cancer that has failed one (and only one) prior chemotherapy regimen. Patients were randomized 2:1 to Orplatna plus prednisone or placebo plus prednisone. Placebo patients were not crossed over to Orplatna after progression. ***The primary efficacy endpoints are progression-free survival (PFS) and overall survival (OS).*** Progression events were adjudicated by a blinded independent committee of radiologists and oncologists.

**The first issue is the definition of one of the two primary endpoints, PFS.** PFS is defined as a composite endpoint, consisting of radiographic progression, symptomatic progression (pain, analgesics, ECOG performance status, weight loss and other clinical events related to prostate cancer) and skeletal related

events. *The FDA has no prior experience with this endpoint. This was clearly communicated to the Applicant during the development phase. FDA will seek ODAC advice on the acceptability of this composite PFS endpoint as the basis of marketing approval.*

Orplatna was better than placebo on the composite PFS endpoint with median PFS 11.1 weeks versus 9.7 weeks ( a median difference of 10 days) and HR 0.67 (0.57, 0.77). Orplatna was also better than placebo on PFS defined as only radiologic progression or death with median PFS 36.3 weeks and 20.0 weeks and HR 0.64 (0.51, 0.81). *Whether this will translate to OS benefit is unknown at this time.*

*The second issue is that the two independent radiology readers disagreed on the progression status in 367 of the 950 patients (39%), requiring adjudication by a third independent radiology reader. This raises the question whether PFS could be reliably assessed in this clinical trial.*

*The third issue regards the assessment of pain progression. Note that pain progression is both part of the composite PFS co-primary endpoint and also the basis for the secondary endpoint of time to pain progression. Because of Orplatna toxicities, it is unlikely that blinding was maintained. In addition, based on a review of background materials provided by the Applicant describing the methods for assessing pain intensity in the SPARC Study, the FDA has determined that the single item Present Pain Intensity Scale (PPI), derived from the McGill Pain Questionnaire (MPQ), has not been adequately validated for use in this study.* The MPQ PPI instrument was used a decade ago in the approval of mitoxantrone for treatment of HRPC, but different criteria for pain response and pain progression were used. Also in the mitoxantrone study the primary endpoint was reduction in pain intensity, while in the Orplatna study the main pain endpoint is time to pain progression. Finally, the FDA Center for Drug Evaluation and Research standards for pain assessment have changed in the interval. In addition, the SPARC protocol did not specify any plan for pain management and pain progression based on increased analgesic use varied widely between countries. Non-narcotic pain medicine usage was not considered in determining pain progression.

*The fourth issue is that only 51% of patients had prior docetaxel. Docetaxel is the only drug shown to improve survival in patients with HRPC. All patients should have had prior docetaxel. However, the SPARC trial was started before FDA approval of*

docetaxel for this use. Subgroup analyses in patients with and without prior docetaxel show that the Orplatna PFS advantage is maintained in both subgroups. Whether there will be a survival advantage in the subgroup with prior docetaxel remains to be seen.

***The fifth issue is whether the FDA should wait for the final survival analysis before taking action on the Orplatna application. An interim analysis of overall survival after 463 deaths does not show that Orplatna is better than placebo.*** The final analysis of overall survival will occur when there are 700 deaths which is estimated to be near the end of 2007.

The main Orplatna toxicity is hematologic with grade 3-4 neutropenia in 21.1% of patients and grade 4 neutropenia in 4.1% of patients. ***Infectious episodes occurred in 23.7% of Orplatna patients compared to 11.5% of placebo patients.*** Grade 3-4 thrombocytopenia occurred in 21.8% of Orplatna patients. Only 2 (0.3%) Orplatna patients had grade 4 thrombocytopenia. ***Gastrointestinal disorders including nausea, vomiting and diarrhea occurred in 58.5% and 29.1% of Orplatna and placebo patients, respectively.*** Only 1.9% of Orplatna patients had grade 3-4 diarrhea and 1.6% had grade 3-4 vomiting.

***Of note, 14 (2.2%) patients with renal failure were reported in the Orplatna group versus 2 (0.6%) in the placebo group.*** Serum creatinine elevations were seen in 20.9% (62/313) of the patients in the placebo group and 17.0% (102/629) of the patients in the Orplatna group. A potential interaction between severe hepatic impairment and development of acute renal failure was suggested by a pharmacokinetic study in which 2 of 5 patients with severe hepatic impairment (Child-Pugh Class C) experienced acute renal failure following 1 or more cycles of Orplatna 80 mg/m<sup>2</sup> dx5 q35d. ***The safety and efficacy of Orplatna in patients with moderate to severe renal impairment, determined by (calculated) creatinine clearance <50 mL/min, have not been established.*** Biochemical markers for renal function (creatinine and BUN) and hepatic function should be monitored prior to initiating each cycle of treatment and as appropriate.

***The EORTC study of similar design to the SPARC study, but in a different patient population (initial chemotherapy in patients with HRPC), was stopped after 50 patients were accrued and provides little support for this NDA.***

***Recommendation is deferred pending ODAC advice on the above issues.*** [Emphasis added.]

44. On this news, the Company's shares declined \$7.80 per share, or over 24.5 percent, to close on July 20, 2007 at \$24.00 per share, on unusually heavy trading volume.

45. On July 23, 2007, the following trading day, WestLB AG cut its recommendation of the Company's securities from "buy" to "hold." On this news, shares of the Company declined an additional \$3.05 per share, or 12.7 percent, to close on July 23, 2007 at \$20.95 per share.

46. Then on July 24, 2007, the FDA panel voted 12-0 to recommend delaying a decision on satraplatin until the Company gathered additional data. As *Bloomberg* reported the following day:

The decline wiped about 180 million euros (\$247 million) from GPC's market value after a panel of advisers to the Food and Drug Administration voted 12-0 yesterday to wait for more data on the treatment, called satraplatin. ***GPC, the company leading the drug's development, said it doesn't expect to have a survival analysis from its 950-patient study for another year.***

\* \* \*

The panel advising the FDA recommended a delay until there is more data on whether satraplatin helped men with prostate cancer live longer. The FDA usually follows the recommendations of its advisers, although it isn't required to do so.

\* \* \*

***Interim data from the clinical test submitted by GPC doesn't prove the drug helps prostate cancer patients live longer, the advisory committee said.*** The panel, which met in Rockville, Maryland, also questioned how the company did its analysis of disease progression and pain reduction in the study.

\* \* \*

GPC said patients who took satraplatin in combination with steroids had a 33 percent lesser risk of cancer spreading than those taking steroids alone. Side effects from the drug were mostly mild and included nausea and fatigue.

"Without additional clinical trials, positive survival data appear to be the only way the drug will ever make it onto the market,"



Friedman Billings Ramsey analyst Robert Uhl wrote today in a note to investors. Uhl cut his rating on Spectrum to "market perform" from "outperform," and reduced his price target for the stock to \$5.50 from \$12.25. [Emphasis added.]

47. On July 25, 2007, *Science Daily*, in relevant part, reported:

The FDA's Oncologic Drugs Advisory Committee in a 12-0 vote Tuesday recommended the agency wait for overall survival data from the SPARC trial before making a decision on approving satraplatin for treating hormone-refractory prostate cancer.

\* \* \*

***GPC had been handling the discussions with the FDA, and it appears the clinical trial design and endpoints for the SPARC study were never signed off on by the agency even though both investors and Spectrum were under the impression they had been. The concerns about the methodology of the trial and the validity of the endpoints appear to have been the main objections of the advisory committee.***

"It would behoove small companies to stay more involved in the development of their products, even after they outlicense them to someone else, because their future is dependent upon it," Uhl told United Press International.

The FDA isn't required to follow the recommendations of its advisory committees but usually does, and analysts expect it to do so in this case. The survival data on satraplatin may not be available until the second half of 2008. [Emphasis added.]

48. Similarly, on July 25, 2007, in an article entitled "You Can't Fight the FDA,"

*Forbes.com*, in relevant part, reported:

There were big hopes for the pill because a clinical trial showed that it reduced the nearly constant pain of patients whose prostate cancer had spread to the bone and had failed other treatments. Better yet, it slowed the cancer's spread, according to a measure devised by the company. Those results were highly statistically significant.

***But both the way pain was measured in the trial and the way that progression of the cancer was gauged were deemed unreliable by the 12-member FDA panel. There was a spectacle at the event, watched via a Webcast. It basically came down to a debate***

*between the company and the FDA in which the FDA insisted, fairly strenuously, that it had let the biotech know that its measures of disease progression and pain were not valid.*

Biotech companies are run by brilliant, somewhat stubborn people who have great faith in their opinions. *Somehow, it sometimes seems, executives can forget that, whatever happens, you can't fight the FDA. If you come up with a brilliant way of proving your drug works but you can't convince the FDA that it's brilliant, you need to come up with another approach.*

\* \* \*

But either the FDA failed to give good guidance or GPC failed to listen. If it had used a more validated measure of patients' pain, the panel might very well have voted to approve its drug. Instead, Otis Brawley, the Emory University oncologist who is the incoming chief medical officer of the American Cancer Society, answered the question of whether satraplatin had been proved to reduce pain with one of the most painful words in biotech: "almost." [Emphasis added.]

49. Also on July 25, 2007, the Company issued a press release entitled "FDA Oncologic Drugs Advisory Committee Recommends that FDA Wait for Overall Survival Results from Satraplatin Phase 3 Trial." Therein, the Company, in relevant part, revealed:

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced that the Oncologic Drugs Advisory Committee (ODAC) for the U.S. Food and Drug Administration (FDA) recommended (12-0) that the FDA should wait for the final survival analysis of the SPARC trial before deciding whether the satraplatin application is approvable for the treatment of hormone-refractory prostate cancer patients whose prior chemotherapy has failed. The FDA is not bound by the recommendations of advisory committees but will consider their advice when reviewing an applicant's NDA.

The Company said that, due to a recent slowing in the reported rate of deaths in the SPARC trial, final overall survival results could take longer than the previously communicated timeframe of the fall of this year.

"While we are extremely disappointed that ODAC has recommended that the FDA wait for the results of the overall survival analysis, we will continue to work with the FDA as the



agency continues its review of the satraplatin application," said Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer of GPC Biotech. "We continue to believe strongly in the potential for satraplatin to help hormone-refractory prostate cancer patients who today have very limited treatment options."

50. On this news, the Company's shares fell an additional \$7.19 per share, or 35.36 percent, to close on July 25, 2007 at \$13.16 per share, on unusually heavy trading volume.

### **POST CLASS PERIOD DEVELOPMENTS**

51. On August 23, 2007, the Company issued a press release entitled "GPC Biotech Announces Restructuring." Therein, the Company, in relevant part

- **Company Implements Leadership Succession Plan for Drug Development Team**

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; NASDAQ: GPCB) today announced a restructuring that will involve U.S. staff reductions of approximately 15 percent of the Company's total workforce. GPC Biotech also announced today that, as part of a succession plan that was put into place in 2006, Martine George, M.D. will succeed Marcel Rozenzweig, M.D. as Senior Vice President, Drug Development and Chief Medical Officer and will assume leadership of the Company's drug development team. Dr. Rozenzweig will remain with the Company in the new role of Senior Vice President, Clinical Science and Drug Evaluation to focus on identifying and pursuing new drug development in-licensing opportunities.

Bernd R. Seizinger, M.D., Ph.D., Chief Executive Officer, said: "The decision to reduce staff has been a very difficult one to make, particularly since we have been able to build and grow such stellar teams. However, these decisions were necessary as we focus on moving the Company forward and planning for our future. I would like to express my sincere appreciation to the affected employees for their important contributions to GPC Biotech. I would also like to emphasize that our belief in satraplatin remains strong and we are committed to doing everything we can to bring satraplatin successfully to the market."

Dr. Seizinger continued: "We hired Dr. Martine George over a year ago as part of a succession plan to ensure a smooth transition in the critical area of drug development, as Dr. Rozenzweig had indicated that he would like to gradually reduce his operational

involvement. Dr. George's extensive experience in driving oncology development at major pharmaceutical companies and her strong contributions since joining GPC Biotech make her well-suited to move our development efforts forward and build on the excellent work of Dr. Rozenzweig. I am happy that Dr. Rozenzweig has agreed to stay with GPC Biotech and help us as we intensify our efforts to in-license promising compounds as well as continue to support us with the preparations for re-filing our NDA for satraplatin based on the overall survival analysis. He is an important member of our senior management team, and his strong network in the oncology community and many years of development experience will continue to be invaluable resources to the Company."

Martine George, M.D. joined GPC Biotech as Senior Vice President, Clinical Development in the spring of 2006. At that time Dr. George, a well-known oncology expert, had over fifteen years of experience at major pharmaceutical companies, as well as several years in an academic position as a medical oncologist. Prior to joining GPC Biotech, Dr. George was Senior Vice President, Head of Oncology at Johnson & Johnson Pharmaceutical Research and Development. Before that she held a number of executive positions in the areas of clinical and medical affairs, including at Rhone-Poulenc Rorer (now part of Sanofi-Aventis), Sandoz Pharmaceuticals Corporation (now Novartis) and American Cyanamid.

The Company's restructuring plan involves a staff reduction of 46 of currently 316 employees or approximately 15% of the total workforce. All affected staff are based in the U.S., with reductions in the commercialization, drug development and general and administrative groups. Affected employees will be eligible for severance packages that include severance pay, continuation of benefits and outplacement services. The Company has retained a core team in all affected functional areas which can serve as a basis for rebuilding in the future. The Company is also retaining the personnel needed to prepare and file as quickly as possible a potential NDA for satraplatin based on overall survival results.

GPC Biotech is also planning to slow down certain ongoing activities and not make further financial commitments to its 1D09C3 monoclonal antibody and cell cycle inhibitors programs at this time. However, the Company plans to maintain the capability to ramp up these programs later, should more resources be available to do so. The Company also plans to continue ongoing satraplatin trials, including the SPERA expanded access program.

**PLAINTIFF'S CLASS ACTION ALLEGATIONS**

52. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased the GPC's securities between December 5, 2005 and July 24, 2007, inclusive (the "Class Period") and who were damaged thereby. Excluded from the Class are defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

53. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, GPC's securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by GPC or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

54. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

55. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

56. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the

questions of law and fact common to the Class are:

- (a) whether the federal securities laws were violated by defendants' acts as alleged herein;
- (b) whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of GPC; and
- (c) to what extent the members of the Class have sustained damages and the proper measure of damages.

57. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

#### **UNDISCLOSED ADVERSE FACTS**

58. The market for GPC's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and misleading statements and failures to disclose, GPC's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired GPC's securities relying upon the integrity of the market price of GPC's securities and market information relating to GPC, and have been damaged thereby.

59. During the Class Period, defendants materially misled the investing public, thereby inflating the price of GPC's securities, by publicly issuing false and misleading

statements and omitting to disclose material facts necessary to make defendants' statements, as set forth herein, not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company, its business and operations, as alleged herein.

60. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, defendants made or caused to be made a series of materially false or misleading statements about GPC's prospects. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of GPC and its prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein.

#### **LOSS CAUSATION**

61. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

62. During the Class Period, Plaintiff and the Class purchased GPC's securities at artificially inflated prices and were damaged thereby. The price of GPC's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

#### **SCIENTER ALLEGATIONS**

63. As alleged herein, defendants acted with scienter in that defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding GPC, their control over, and/or receipt and/or modification of GPC's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning GPC, participated in the fraudulent scheme alleged herein.

64. Additionally, during the Class Period, and the Company's securities trading at artificially inflated prices, GPC generated significantly superior levels of capital through its financing activities. For example, on February 24, 2006, the Company was able to raise € 36.2 million in a private placement of its securities, whereby it sold 2.86 million of the Company's shares at a price of € 12.67 per share. Then on January 24, 2007, the Company was able to raise an additional € 33.6 million in another private placement of its securities, this time by selling an additional 1.5 million of the Company's shares at a price of € 21.50 per share.

65. Also, on December 20, 2005, and as a result of the Company's false and misleading statements, the Company was able to complete a co-development and licensing agreement for the commercialization of satraplatin. In exchange for \$37.1 million (with provisions which enabled the Company to receive as much as \$270 million), which provided the Company with desperately needed capital necessary for the Company's continued survival, GPC successfully licensed away the commercialization rights for satraplatin in Europe, Australia, the

Middle East, and other areas of the world.

**Applicability of Presumption of Reliance:  
Fraud On The Market Doctrine**

66. At all relevant times, the market for GPC's securities was an efficient market for the following reasons, among others:

- (a) GPC's securities met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;
- (b) As a regulated issuer, GPC filed periodic public reports with the SEC and the NASDAQ;
- (c) GPC regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- (d) GPC was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

67. As a result of the foregoing, the market for GPC's securities promptly digested current information regarding GPC from all publicly-available sources and reflected such information in GPC's securities price. Under these circumstances, all purchasers of GPC's securities during the Class Period suffered similar injury through their purchase of GPC's securities at artificially inflated prices and a presumption of reliance applies.

**NO SAFE HARBOR**



68. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of GPC who knew that those statements were false when made.

**FIRST CLAIM**  
**Violation of Section 10(b) of**  
**The Exchange Act and Rule 10b-5**  
**Promulgated Thereunder Against All Defendants**

69. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

70. During the Class Period, defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase GPC's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

71. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made

untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for GPC's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

72. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about GPC's prospects, as specified herein.

73. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of GPC's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about GPC and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of GPC's securities during the Class Period.

74. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's

management team or had control thereof; (ii) each of these defendants, by virtue of his responsibilities and activities as a senior officer and/or director of the Company was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

75. The defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing GPC's prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by defendants' overstatements and misstatements of the Company's prospects throughout the Class Period, defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

76. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of GPC's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of GPC's securities were artificially inflated, and relying directly or indirectly on the false and misleading

statements made by defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by defendants, but not disclosed in public statements by defendants during the Class Period, Plaintiff and the other members of the Class acquired GPC's securities during the Class Period at artificially high prices and were damaged thereby.

77. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that GPC was experiencing, which were not disclosed by defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their GPC securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

78. By virtue of the foregoing, defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

79. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

**SECOND CLAIM**  
**Violation of Section 20(a) of**  
**The Exchange Act Against the Individual Defendants**

80. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

81. The Individual Defendants acted as controlling persons of GPC within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level

positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

82. In particular, each of these defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

83. As set forth above, GPC and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

**WHEREFORE**, Plaintiff prays for relief and judgment, as follows:

- (a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

- (b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- (c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
- (d) Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Dated: August 23, 2007

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